

PART F

X-RAYS IN THE HEALING ARTS

1. **Scope.** This part provides for the registration of radiation machine facilities, and establishes requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

2. **Definitions.** As used in this part, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration that is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy ^{1/} affording the same attenuation, under specified conditions, as the material in question.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy ^{1/} or other materials having equivalent attenuation.

Automatic exposure control means a device that automatically controls one or more technique, factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as photo timers and ion chambers).

Barrier (See "Protective barrier").

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system means a system designed to detect and measure the radiation present in the useful beam.

C-arm x-ray system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient. This definition does not refer to a conventional fluoroscopic system or to a dental cephalometric x-ray machine.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components mean components of x-ray systems, which components are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified system means any x-ray system that has one or more certified component(s).

Changeable filters means any filter, exclusive of inherent filtration, which filter can be removed from the useful beam through any electronic, mechanical or physical process.

^{1/} The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

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Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{\sigma}{\bar{w}} = \frac{1}{\bar{w}} \left[\sum_{i=1}^n \frac{(\omega_i - \bar{w})^2}{n - 1} \right]^{1/2}$$

where

σ = Estimated standard deviation of the population.

\bar{w} = Mean value of observations in sample.

ω_i = with observation in sample.

n = Number of observations in sample

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact therapy system means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

CT (see Computed tomography).

Dead-man switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray imaging system means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation, which has been deviated in direction only by materials, irradiated by the useful beam (See "Scattered radiation").

Direct supervision means that during use of the radiation producing sources and devices, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is using the radiation producing sources and devices.

Entrance exposure rate means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

Field emission equipment means equipment, which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot (actual) means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system, which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form, which can be made into a visible image by further transformations.

Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor during a mammography.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See "Peak tube potential").

kV means kilovolts. "kVp" (See "Peak tube potential").

kWs means kilowatt second.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

- (a) the useful beam, and
- (b) radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic assembly which are used in measuring leakage radiation. They are defined as follows:

- (a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.
- (b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

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Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_1) / V_1$$

where

V_n = No-load line potential and

V_1 = Load line potential.

mA means milliamperes.

mAh means milliamperes second.

Mammographic Facility means a facility that has an x-ray machine that is used, exclusively or not, for taking breast radiographs. Some facilities, such as hospitals, may have mammographic x-ray machines. These x-ray machines shall comply with the rules, which apply to mammographic facilities.

Maximum line current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile x-ray equipment (See "X-ray equipment").

Mobile Van means an x-ray facility housed within a vehicle, which facility is moved, or capable of being moved to different locations for the purpose of performing x-ray examinations.

PBL (Positive beam limitation) means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit, which controls the duration of time the tube is activated (See "Automatic exposure control").

PID (See "Position indicating device").

Portable C-arm x-ray system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship

Portable x-ray equipment (See "X-ray equipment")

Position indicating device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skew) distance. It may or may not incorporate or serve as a beam-limiting device.

Primary dose monitoring system means a system that will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier (See "Protective barrier").

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (a) Primary protective barrier means the material, excluding filters, placed in the useful beam.
- (b) Secondary protective barrier the material which attenuates stray radiation.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Quality assurance program means a program, including quality control, which program extends to administrative, educational, and preventive maintenance methods. For purposes of these rules, a QA program is directed at radiographic facilities and includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program.

Quality control means a series of distinct technical procedures with the aim to provide high quality images while emitting as low a dose as necessary. QC includes, but is not limited to, the frequent evaluations of film processing, cassettes and intensifying screens, the film and the x-ray equipment.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic imaging system means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Response time means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

Secondary dose monitoring system means a system that will terminate irradiation in the event of failure of the primary system.

Secondary protective barrier (See "Protective barrier").

Shutter means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See "Source-image receptor distance").

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Spot check means a procedure that is performed to assure that a previous calibration, continues to be valid.

Spot film means a radiograph that is made during a fluoroscopic examination to permanently record conditions, which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

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SSD means the distance between the source and the skin entrance plane of the patient.

Stationary x-ray equipment (See "X-ray equipment").

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

- (a) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (b) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
- (c) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, on the product of tube current and exposure time in mAs.

Termination of irradiation means the stopping of irradiation in a fashion, which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Traceable to a National Standard means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture beam-limiting device means a beam-limiting device, which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray exposure control means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components, which function with the system, are considered integral parts of the system.

X-ray tube means any electron tube that is designed to be used primarily for the production of x-rays.

3. General Requirements.

A. Administrative Controls.

- (1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of F.3.A.(1) are met in the operation of the x-ray system(s).
 - (a) Any x-ray system (whether certified or non-certified) which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes unless a written exception is received from the Agency. See Section F.3.D.
 - (b) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The licensing requirements pursuant to 32 MRSA Chapters 103 § 9851 et seq and 331 § 1100 I et seq as well as the associated rules established by the Radiologic Technology Board of Examiners and the Board of Dental Examiners shall be followed.
 - (c) Except for intraoral and extra-oral dental radiography, a chart shall be provided in the vicinity of the diagnostic x-ray system's control panel. If the posting in the vicinity of the control panel is not practical, it shall be conspicuously available to users of the equipment. The following information shall be specified on the chart:
 - (i) patient's anatomical size versus technique factors to be utilized,
 - (ii) type and size of the film or film-screen combination to be used,
 - (iii) type and focal distance of the grid to be used, if any,
 - (iv) source to image receptor distance to be used; and
 - (d) Written safety procedures and rules shall be posted in the vicinity of each x-ray control panel, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures. Copies of certificates of those individuals duly authorized to perform such x-rays shall be conspicuously posted.
 - (e) Except for human patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - (i) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.
 - (ii) The x-ray operator, other staff, ancillary personnel and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

F.3.A(1)(e)

- (iii) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
- (f) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- (g) Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 - (i) Exposure of an individual for training, demonstration or other non-healing-arts purposes; and
 - (ii) exposure of an individual for the purpose of healing arts screening except as authorized by F.3.A.(1)(k).
- (h) When a patient or film must be provided with auxiliary support during a radiation exposure:
 - (i) mechanical holding devices shall be used when the technique permits;
 - (ii) written safety procedures, as required by F.3.A.(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 - (iii) the human holder shall be instructed in personal radiation safety and be protected as required by paragraph F.3.A.(1)(e).
 - (iv) no individual shall be used routinely to hold film or patients; and
 - (v) in those cases where the patient must hold the film, except during intraoral or extra-oral dental examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and
 - (vi) each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
- (i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
 - (i) The screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of standard film packets for intra-oral use in dental radiography.
 - (ii) Portable or mobile equipment shall only be used in cases where it is impractical to transfer the patient(s) to a stationary x-ray unit. Portable equipment is not to be used as a substitute for a stationary unit.
 - (iii) Film processing is to be conducted in accordance with the manufacturer's instructions.
- (j) All individuals who are associated with the operation of an x-ray system are subject to the requirements of D.1201, D.1206 and D.1502 of these regulations. In addition:
 - (i) When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

F.3.A(1)(j)

- (ii) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.
 - (iii) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by D.2106 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
 - (iv) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
 - (k) Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.
- (2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system or, as appropriate, facility, for inspection by the Agency:
- (a) model and serial numbers of all certifiable components, if readily available;
 - (b) aluminum equivalent filtration of the useful beam, including any routine variation;
 - (c) records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of these rules with the names of persons who performed such services;
 - (d) for all facilities constructed or modified after January 1, 1986, a scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room, an estimation of the extent of occupancy by an individual in such areas, and the location of the x-ray machine. In addition, the drawing shall include:
 - (i) the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or
 - (ii) the type and thickness of materials, or lead equivalency, of each protective barrier; and
 - (e) a copy of all correspondence with this Agency regarding that x-ray system.
 - (f) a copy of the facility's x-ray quality assurance program. (See Section F.5.I.)
- (3) X-ray Patient Record. Each facility shall have available for inspection a record (either paper or electronic) or other such document identifying the patient by number or name, the type of examination, the date, the room where the examination was performed, and who performed the x-ray.

B. Shielding Requirements and Plan Review.

- (1) Prior to initial operation, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Agency. The required information is denoted in Appendices A and B of this part.
- (2) The applicant shall utilize the services of a Radiological Physicist to determine the shielding requirements prior to plan review and approval by the Department. In determining the shielding requirements for dental x-ray facilities, the Department may authorize other professionals, providing their qualifications justify such an authorization.

- (3) The submittal of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in D.1201, D.1207 and D.1301 of these regulations.

F.3.C

C. Initial and Periodic Survey.

- (1) Pursuant to 22 MRSA section 682 duly authorized employees of the Department of Health and Human Services may enter into establishments during working hours to determine whether there is compliance with provisions of the Radiation Protection Act.
- (2) Departmental Certification of Technicians, as authorized by 22 MRSA section 682(3), designated as Qualified Experts, and authorized by the Department shall be utilized to perform inspection and calibration services, and to certify x-ray and/or teletherapy units (see section G.4.D and G.4.E).
- (3) Existing facilities: Except as stated in section F.3.C.4., the licensee of all existing x-ray facilities shall have each x-ray machine and tube inspected at the following minimum frequency:
 - (a) Hospitals - prior to January 1, 1987 and once every year thereafter;
 - (b) Mammographic Facilities - prior to January 1, 1991, and every year thereafter
 - (c) Dental Facilities - prior to January 1, 1988 and once every three years thereafter;
 - (d) Podiatric - prior to January 1, 1987 and once every three years thereafter;
 - (e) Veterinary - prior to January 1, 1987 and once every five years thereafter;
 - (f) All Others - prior to January 1, 1987 and once every two years thereafter.
- (4) The periodic Quality Control survey, conducted at the above stated frequencies, are not covered by the annual registration fee but are in addition to that fee. When the inspections are carried out by third-party, non-state technicians, the fee is determined by the inspector and the facility.
- (5) Except for intra-oral, panorex, mammographic and podiatric x-ray machines, all new facilities and existing facilities adding new machines shall have a survey made by a Qualified Expert within 30 days. The intra-oral, panorex and podiatric machines shall be inspected within 12 months. Mammographic facilities shall be inspected by a Qualified Expert prior to operation. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. See F.4.
- (6) The registrant shall obtain a written report of the survey from the Qualified Expert and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
- (7) Upon notification or discovery of a violation to the Rules stated in this section, the Department may, in its notice of violation to the licensee, require a re-inspection, by a Qualified Expert. This increase in frequency of inspection will depend upon the severity of the violation.

D. Exemptions.

- (1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of Part F, providing the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 mSv (0.5 mrem) per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.
- (2) Radiation machines while in transit or storage incident thereto are exempt from the requirements of Part F.
- (3) Domestic television receivers are exempt from the requirements of this part.

- (4) Exemptions to the requirements of Part F may be granted, provided written justification is submitted by a Qualified Expert.

E. Applications for Registration of Radiation Machine Facilities.

F.3.E(1)

- (1) Each person having a radiation machine facility shall apply for registration of such facility with the Agency following the effective date of these regulations or thereafter prior to the operation of a radiation machine facility. Application for registration shall be completed on form HHE 805 "X-Ray Registration Form" furnished by the Agency and shall contain all the information required by the form and accompanying instructions. As a minimum, the form shall include the following information.
 - (a) Name, address, and telephone number of the following:
 - (i) The radiation machine facility.
 - (ii) The owner of the radiation machine facility.
 - (iii) The individual responsible for the use of the facility.
 - (iv) The individual responsible for radiation protection at the facility.
 - (b) The manufacturer, model number, and type of each radiation machine located within the facility.
 - (c) The signature of the individual designated as the Qualified Expert..
 - (d) Name of the radiation machine supplier, installer, and service agent.
 - (e) The date of application and signature of the individual responsible for the use of the facility.
- (2) Registration Fee.
 - (a) A registration fee for each x-ray tube shall be paid annually. Appendix F to this Part provides the schedule of fees.
 - (b) Submit a check payable to the Treasurer of State along with the application for annual registration for the appropriate amount specified.
- (3) The licensee of all x-ray facilities shall have each x-ray machine and tube inspected in accordance with the requirements of Section F.3.C.

F. Application for Registration of Servicing and Services

- (1) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency within 30 days following the effective date of this regulation or thereafter prior to furnishing or offering to furnish any such services.
- (2) Application for registration shall be completed on form HHE 825 "Registration of Servicing and/or Services Employee Exposure Form" furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions. No fee required.
- (3) Certification and Registration of Qualified Experts for the conducting of the periodic survey is covered in Part F.4.
- (4) The service representative shall notify the agency in writing of any address, telephone or personnel changes.

G. Issuance of Notice of Registration.

- (1) Upon a determination that the requirements of Part F.3.E have been met, the Agency shall issue a notice of registration.
- (2) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary.

F.3.H

- H. Expiration of Notice of Registration. Except as provided by F.3.I each notice of registration shall expire at the end of the specified day in the month and year stated therein, or upon notice issued to the registrant by the Agency.
- I. Renewal of Notice of Registration.
 - (1) Application for renewal of registration shall be filed annually and in accordance with Part F.3.E.(2) Application for renewal of registration and notification of current expiration date will be provided to each licensee by the Agency at least 60 days prior to the expiration date.
 - (2) In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.
- J. Report of Changes. The registrant shall notify the Agency in writing before making any changes which would render the information contained in the application for registration and/or the notice of registration no longer accurate.
- K. Approval Not Implied. No person, in any advertisement, shall refer to the fact that his or her facility is registered with the Agency pursuant to these provisions, and no person shall state or imply that any activity under such registration has been approved by the Agency.
- L. Assembler and/or Transfer Obligation.
 - (1) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the Agency within 15 days of:
 - (a) the name and address of persons who have received these machines;
 - (b) the manufacturer, model, and serial number of each radiation machine transferred; and
 - (c) the date of transfer of each radiation machine.
 - (d) in the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.
 - (2) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and use, meet the requirements of these regulations.
- M. Out-of-State Radiation Machines.
 - (1) Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Agency at least 2 working days before such machine is to be used in the State. The notice shall include:
 - (a) the type of radiation machine;
 - (b) the nature, duration, and scope of use;
 - (c) the exact location(s) where the radiation machine is to be used; and
 - (d) the states in which this machine is registered.
 - (2) If, for a specific case, the two working-day period would impose an undue hardship on the person, upon notification to the Agency, permission to proceed sooner may be granted.
 - (3) The person referred to in F.3.M.(1) shall:
 - (a) comply with all applicable regulations of the Agency, to include the necessary inspection and registration fees;

F.3.M(3)(b)

- (b) supply the Agency with such other information as the Agency may reasonably request; and
- (c) not operate within the State on a temporary basis in excess of 90 calendar days per year.

4. Certification of Qualified Experts. The Department shall certify Qualified Experts for the purpose of inspecting, and certifying x-ray equipment to establish compliance with these regulations. The Department may grant, modify or refuse to issue a certification in accordance with the Maine Administrative Procedure Act, Title 5, Chapter 375, Subchapter V.

A. Radiological Physicist Certification

- (1) The Radiological Physicist, except as provided for in section F.3.C.(4), shall be responsible for the preparation and issuance of all inspection reports, and shall be accountable for all information, findings and recommendations contained therein.
- (2) Certification shall be in the diagnostic x-ray and/or the therapy area. To be eligible to apply for certification as a Radiological Physicist an individual shall, in addition to satisfying the training and experience requirements of Part A of these regulations,
 - (a) Not be currently employed by any company offering sales or service of x-ray equipment; and
 - (b) Be certified by the American Board of Radiology in diagnostic radiologic physics; or
 - (c) Be certified by the American Board of Health Physics and have one year of experience in the area of diagnostic x-ray as outlined in Appendix D; or
 - (d) Possess a Masters Degree in a Physical Science and have three years experience in the area of diagnostic x-ray as outlined in Appendix D.
- (3) Individuals meeting the above qualifications may apply to the Department for certification using Agency form HHE 820 "Certified Technician Registration Form". The application shall include the following information as a minimum:
 - (a) Name and address
 - (b) Telephone number
 - (c) Detailed description of Education
 - (d) Detailed description of Experience
 - (e) List of measuring and calibration equipment used
 - (f) Types of services to be provided
- (4) Upon receipt and review of an application, the Department may require additional submissions and/or personal interviews with the applicant if deemed necessary to issue a certification.

B. X-Ray Survey Technician Certification

- (1) The X-Ray Survey Technician shall be responsible for the collection of data used in the preparation of inspection reports and shall collect such data only under the supervision of a Radiologic Physicist.
- (2) To be considered eligible to apply for certification as an X-Ray Survey Technician an individual shall in addition to satisfying the training and experience requirements of Part A of these regulations, also not be currently employed by any company offering sales or service of x-ray equipment..

C. Application for Certification.

- (1) Individuals meeting the above qualifications may apply to the Department for Certification using Agency form HHE 820 "Certified Technician Registration Form". The application shall include the following information as a minimum:

F.4.C(1)(a)

- (a) Name and address
 - (b) Telephone number
 - (c) Detailed Description of Education, include transcripts
 - (d) Detailed Description of Experience, include resume
 - (e) Name of Certified Radiologic Physicist for whom the technician will be working, if applicable.
 - (f) A statement from the Radiologic Physicist outlining the types of surveys the applicant is qualified to perform, if applicable.
- (2) Upon receipt and review of an application the Department may require additional submission and/or personal interviews with the applicant if deemed necessary to issue a certification.
- (3) All certificates issued by the Department shall be valid for a period of five (5) years from the date of issue. Six months prior to expiration, the Department shall review the record of each individual whose certification is due to expire, and upon request of that individual issue a new certificate.
- D. Radiation Instrument Calibrations. Pursuant to Part D.1501, of these Regulations, all radiation measuring instruments shall be "calibrated" at intervals not to exceed 12 months. Additionally, Mammography Quality Standards Act (MQSA) requirements shall continue to be recognized where applicable.

5. General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

- A. Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- B. Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- C. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 10 μ Sv (100 mr) (25.8 mC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- D. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 20 μ Sv (2 mr) (0.516 mC/kg) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- E. Beam Quality.
 - (1) Half-value Layer.
 - (a) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1. If it is necessary to determine such half-value layer at an x-ray tube potential, which is not listed in Table 1, linear interpolation or extrapolation may be made.

TABLE 1

| Design operating range (Kilovolts peak) | Measured potential (kVp) | Minimum HVL (mm of AL) | |
|--------------------------------------------|--------------------------------|---------------------------------|------------------------------------------|
| | | Specified dental systems* | All other diagnostic X-ray systems |
| Below 50----- | 30 | 1.5 | 0.3 |
| | 40 | 1.5 | 0.4 |
| | 49 | 1.5 | 0.5 |
| 50 to 70----- | 50 | 1.5 | 1.2 |
| | 60 | 1.5 | 1.3 |
| | 70 | 1.5 | 1.5 |
| Above 70----- | 71 | 2.1 | 2.1 |
| | 80 | 2.3 | 2.3 |
| | 90 | 2.5 | 2.5 |
| | 100 | 2.7 | 2.7 |
| | 110 | 3.0 | 3.0 |
| | 120 | 3.2 | 3.2 |
| | 130 | 3.5 | 3.5 |
| | 140 | 3.8 | 3.8 |
| | 150 | 4.1 | 4.1 |

* for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980;

- (b) The requirements of F.5.E.1(a) will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 2.

TABLE 2

Filtration Required vs. Operating Voltage

| Total Filtration (inherent plus added) | |
|-------------------------------------------|------------------------------------------|
| <u>Operating Voltage (kVp)</u> | <u>(millimeters aluminum equivalent)</u> |
| Below 50 ----- | 0.5 |
| 50 - 70 ----- | 1.5 |
| Above 70 ----- | 2.5 |

- (c) The required minimal half value layer of the useful beam shall include the filtration contributed by all materials, which are permanently between the source and the patient.
- (2) Filtration Controls. For x-ray systems constructed after 1974, which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by F.5.E.(1). is in the useful beam for the given kVp, which has been selected.

F.5.F

- F. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes, which have been selected, shall be clearly indicated prior to initiation of the exposure. This indication shall be on the x-ray control panel.
- G. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- H. Technique Indicators.
 - (1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used the technique factors which are set prior to the exposure shall be indicated.
 - (2) The requirement of F.5.H(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operators position except in the case of spot films made by the fluoroscopist.
- I. Quality Assurance Program
 - (1) Each hospital, out-patient clinic, chiropractic, and private medical facility, to include approved screening programs that are performing diagnostic x-rays on humans shall establish an active quality assurance program. The quality assurance program shall incorporate the standards and records indicated in Appendix G, Quality Assurance Requirements for Facilities Performing Diagnostic X-Ray.
 - (2) The QA program for mammographic facilities shall be inspected by the department annually. All other, non-dental, radiographic facilities, shall have their QA program inspected by the department prior to the end of the periodic survey time frame.
 - (3) Locks, all position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

6. Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems shall be image intensified and meet the following requirements:

- A. Limitation of Useful Beam.
 - (1) Primary Barrier.
 - (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier, which intercepts the entire cross section of the useful beam at any SID.
 - (b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.
 - (2) Fluoroscopic Beam Limitation.
 - (a) Certified fluoroscopic systems, with or without "spot" film device neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
 - (i) means shall be provided to permit further limitation of the field. Beam limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with a means for stepless adjustment of the x-ray field;
 - (ii) all equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;
 - (iii) if provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less.

F.6.A(2)(a)(iv)

- (iv) for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
- (v) For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- (b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.
- (c) For uncertified fluoroscopic systems without a spot film device, the requirements of F.6.A(2)(a) apply.
- (d) Other requirements for fluoroscopic beam limitation:
- (e) Spot-film devices, which are certified components, shall meet the following additional requirements:
 - (i) means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film, which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
 - (ii) it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film;
 - (iii) the center of the x-ray field in the plane of film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and
 - (iv) on spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- B. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device, which requires continuous pressure, by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- C. Exposure Rate Limits.
 - (1) Entrance Exposure Rate Allowable Limits
 - (a) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 100mSv (10R) (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:
 - (b) during recording of fluoroscopic images, or

F.6.C(1)(c)

- (c) when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 50mSv (5R) (1.29 mC/kg) per minute (for fluoroscopic equipment manufactured before May 1995) or 5.16 mC/kg (20 Roentgens) per minute (for fluoroscopic equipment manufactured on or after May 1995) at the point where the center of the useful beam enters the patient. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (d) Compliance with the requirements of F.6.C shall be determined as follows:
 - (i) If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.
 - (ii) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - (iii) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
 - (iv) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.
- (e) Periodic measurement of entrance exposure rate shall be performed as follows:
 - (i) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
 - (ii) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in F.3.A(2)(c). The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.
 - (iii) Conditions of periodic measurement of entrance exposure rate are as follows:
 - (a) the measurement shall be made under the conditions that satisfy the requirements of F.6.C.1(d);
 - (b) the kVp and MA shall be typical of clinical use of the x-ray system;
 - (c) the x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and
 - (d) x-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.^{2/}

^{2/} Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

D. Barrier Transmitted Radiation Rate Limits.

- (1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 20 μ Sv (2mr) (0.516 mC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
- (2) Measuring Compliance of Barrier Transmission.
 - (a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
 - (b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
 - (c) If the source is above the tabletop and the SID is variable, the measurement shall be made, if practicable, with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
 - (d) Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - (e) The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

E. Indication of Potential and Current. During fluoroscopy and cinefluorography, the kV and the mA or mAs shall be continuously indicated.**F. Source-skin Distance.** The SSD shall not be less than:

- (1) 38 centimeters on stationary fluoroscopes installed after the effective date of this regulation,
- (2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to the effective date of these regulations,
- (3) 30 centimeters on all mobile fluoroscopes, and
- (4) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

G. Fluoroscopic Timer.

- (1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
- (2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.
- (3) Fluoroscopic on time shall be recorded.

H. Mobile fluoroscopes. In addition to the other requirements of F.6.F, mobile fluoroscopes shall provide intensified imaging.**I. Control of Scattered Radiation.**

- (1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

F.6.I(2)

- (2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:
 - (a) is at least 120 centimeters from the center of the useful beam, or
 - (b) the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to drapes, Bucky-slot cover panel, or self supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in F.3.A.(1)(e)
- (3) The Agency may grant exceptions to F.6.I(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

J. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of F.6.A, F.6.C, F.6.D, and F.6.H provided that:

- (1) such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
- (2) systems, which do not meet the requirements of F.5.H, are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the times be reset between examinations.

7. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral or Veterinarian Systems.

A. Beam Limitation. The useful beam shall be limited to the area of clinical interest.

- (1) General Purpose Stationary and Mobile X-Ray Systems.
 - (a) There shall be provided a means for stepless adjustment of the size of the x-ray field.
 - (b) For those units so designed, a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
 - (c) The Agency may grant an exemption on non-certified x-ray systems to F.7.A.(1)(a) and (b) provided the registrant makes a written application for such exemption and in that application:
 - (i) demonstrates it is impractical to comply with F.7.A.(1)(a) and (b); and
 - (ii) the purpose of F.7.A.(1)(a) and (b) will be met by other methods.
- (2) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.7.A.(1), all stationary general purpose x-ray systems shall meet the following requirements:
 - (a) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;
 - (b) the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

- (c) indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

F.7.A(4)(b)

- (3) X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- (4) Mammography Equipment Standards. Only x-ray systems meeting the following standards shall be used:
 - (a) System design: The x-ray system shall be specifically designed for mammography.
 - (b) Image receptor: The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.
 - (c) Radiographic systems designed for mammography shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system, which performs as prescribed in F.7.A.(5).
- (5) Special Purpose X-Ray Systems.
 - (a) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - (b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
 - (c) F.7.A(5)(a) and (b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.7.A(1) or, when alignment means are also provided, may be met with either:
 - (i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
 - (ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

B. Radiation Exposure Control Devices.

- (1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the time is set to a "zero" or "off" position if either position is provided.
- (2) Manual Exposure Control.

- (a) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
 - (i) exposure of one-half (1/2) second or less, or

F.7.B(2)(a)

- (ii) during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
- (b) Each x-ray control shall be located in such a way as to meet the following requirements:
 - (i) stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
 - (ii) mobile and portable x-ray systems which are:
 - (a) used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of F.7.B.(2)(b)(i)
 - (b) used for greater than 1 hour and less than 1 week at the same location, i.e., 1 room or suite, shall meet the requirement of F.7.B.(2)(b)(ii)(a) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed at least 6 (1.83m) feet from the tube housing assembly and at least 6 (1.83m) feet from the patient; or
 - (c) used to make an exposure(s) of a patient at the use location shall meet the requirement of F.7.B.(2)(b)(ii)(a) or(b) or be provided with a method or x-ray control which will permit the operator to be at least 6 feet (3.66m) from the tube housing assembly during an exposure.
 - (iii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator, if available with the unit, shall indicate that the exposure has terminated.
- (3) Automatic Exposure Controls. When an automatic exposure control is provided:
 - (a) indication shall be made on the control panel when this mode of operation is selected;
 - (b) if the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
 - (c) the minimum exposure time for all equipment other than that specified in F.7.B.(3)(b) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
 - (d) either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
 - (e) a visible signal shall indicate when an exposure has been terminated at the limits required by F.7.B(3)(d), and manual resetting shall be required before further automatically timed exposures can be made.
- (4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure (Tmin) when 4 timer tests are performed; i.e., $T \geq 5 (T_{max} - T_{min})$.
- C. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters.
- D. Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin), i.e., $E \geq 5 (E_{max} - E_{min})$.

F.7.E

E. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 20 μSv (2mr) (0.516 mC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

F. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperes-seconds product, i.e., mR/mAs, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum,

$$X1-X2 \leq 0.10 (X1 + X2),$$

where X1 and X2 are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of the manufacturer's specifications the deviation shall not exceed 10% of the indicated value.

(4) Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

(a) There shall be provided a means of stepless adjustment of the size of the x-ray field.

(b) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on or after May 27, 1980, are exempt from this requirement.

(c) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as $I1/I2$ when $I1$ is the illumination 3 millimeters from the edge of the light field toward the center of the field; and $I2$ is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(5) Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.7.A.(1). and F.7.F.(4).

(6) Field Limitation and Alignment on Stationary General Purpose X-Ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c):

(a) Positive beam limitation (PBL) when present shall function whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are each less than 50 centimeters;

F.7.F(6)(a)

- (iii) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;
 - (vi) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;
 - (v) Neither tomographic nor stereoscopic radiography is being performed; and
 - (vi) The PBL system has not been intentionally overridden. This override provision is subject to F.7.F.(6)(c).
- (b) Positive beam limitation (PBL) shall prevent the production of x-rays when:
- (i) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.7.F(6)(e) from the corresponding image receptor dimensions by more than 3 percent of the SID; or
 - (ii) The sum of the length and width differences as stated in F.7.F.(6)(b)(i) without regard to sign exceeds 4 percent of the SID.
- (c) If a means of overriding the positive beam limitation (PBL) system exists, that means:
- (i) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and
 - (ii) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator,
 - (a) shall require that a key be utilized to defeat the PBL;
 - (b) shall require that the key remain in place during the entire time the PBL system is overridden; and
 - (c) shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

- (d) Compliance with F.7.F.6(b) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of F.7.F.(6)(a) are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.
 - (e) The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size.
 - (f) The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in F.7.F.(6)(b), then any change of image receptor size or SID must cause the automatic return.
- (7) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

F.7.F(8)

- (8) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 1 μ Sv (0.1 mr) (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rate peak tube potential for the system and at the maximum rated product of the tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

8. Intraoral Dental Radiographic Systems and Podiatric Systems. In addition to the provisions of F.3, F.4, and F.5, the requirements of F.8 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.7.

- A. Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than:
- (1) 18 centimeters if operable above 50 kVp, or
 - (2) 10 centimeters if operable at 50 kVp.
- B. Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
- (1) if the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and
 - (2) if the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters .
- C. Radiation Exposure Control for Certified and Non-Certified Systems.
- (1) Exposure Initiation
 - (a) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and
 - (b) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
 - (2) Exposure Termination
 - (a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
 - (b) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.
 - (c) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero"
 - (3) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

F.8.C(4)

- (4) Exposure Duration (Timer) Reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (Tmax) and the minimum exposure time (Tmin) shall be less than or equal to 10 percent of the average exposure time (T), when four timing tests are performed:

$$(T_{\max} - T_{\min}) < 0.10T$$

D. X-Ray Control.

- (1) Each x-ray control shall be located in such a way as to meet the following requirements:
- (a) stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area, and the operator is required to remain in that protected area, or 6 feet away and out of the useful beam during the entire exposure; and
 - (b) mobile and portable x-ray systems which are:
 - (i) used for greater than 1 week in the same location, i.e. a room or suite, shall meet the requirements of F.8.D(1)(a);
 - (ii) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of F.8.D(1)(b)(i) or be provided with a 6.5 (1.98m) foot high protective barrier which is placed at least 6 feet (1.98m) from the tube housing assembly and at least 6 feet (1.98m) from the patient; or
 - (iii) used to make an exposure(s) of a patient at the use location shall meet the requirement of F.8.D(2)(b)(i) or (ii) or be provided with a method of x-ray control which will permit the operator to be at least 6 feet (3.66m) from the tube housing assembly and out of the useful beam during an exposure.
- (2) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator, if available to the unit, shall indicate that the exposure has terminated.

- E. Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (Emax), minus the minimum exposure (Emin):

$$\text{i.e., } E \geq 5(E_{\max} - E_{\min}).$$

F. Administrative Controls.

- (1) Patient and film holding devices shall be used when the techniques permit.
- (2) The tube housing and the PID shall not be hand-held during an exposure.
- (3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.8.B.(1).
- (4) Dental fluoroscopy without image intensification shall not be used.

- G. Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirements(s) which relate to that certified component(s).

- (1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

F.8.G(2)

- (2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperere-seconds product, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum,

$$\text{i.e., } X1-X2 \leq 0.10 (X1 + X2),$$

where X1 and X2 are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

- (3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of the manufacturer's specifications the deviation shall not exceed 10% of the indicated value.
- (4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
- (5) Beam Quality. All certified dental x-ray systems manufactured on or after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.5.E.(1).

9. Veterinary Medicine Radiographic Installations.

A. Equipment.

- (1) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
- (2) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent.
- (3) A device shall be provided to terminate the exposure after a preset time or exposure.

B. Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with D.1201, D.1207 and D.1301 of these regulations.

C. Operating Procedures.

- (1) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.
- (2) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he/she shall be so positioned that no part of his/her body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

10. Mobile Service.

A. In addition to the requirements of machine registration, inspection, and QA, any mobile service provider before beginning such service shall submit to the Maine Radiation Control Program the following:

- (1) An established main location where the machines, records, etc, will be maintained for inspection. This must be a street address, not a P.O. Box.
- (2) A current copy of an inspection report performed by an approved Qualified Expert.
- (3) Copies of the applicant's operating, safety, and emergency procedures for the protection of patients, operators, facility employees, and the public.

- (4) A list of mobile service employees.

F.10.A(5)

- (5) A list of facilities where mobile service will be provided.
- (6) A list of licensed practitioners who interpret the radiographs.

11. Mobile Vans.

- A. In addition to meeting all the requirements of machine registration, inspections, and QA, any mobile van with on board processing shall drain the processor tanks in an approved location between each temporary site.
- B. Mobile mammographic vans shall perform phantom images after each relocation.

12. Bone Densitometry. In addition to other requirements of this part, all x-ray bone densitometry systems shall meet the following requirements:

- A. The requirement for having a shielding design performed by a Qualified Expert for bone densitometry units has been waived.
- B. An inspection of the unit and an environmental survey of the area shall be performed, before patient examination to ensure that radiation levels to members of the general public outside the exam room are within regulatory limits. A copy of this report must be sent to the Maine Radiation Control Program.
- C. The console shall be positioned such that the operator is at least 1 meter from the scan field
- D. Access to the exam room during a scan shall be controlled by the operator to prevent exposure to other personnel and the general public.

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice and official approval on shielding requirements for a radiation installation, the following information must be submitted.

- A. The plans should show, as a minimum, the following:
 - (1) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
 - (2) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room(s) concerned.
 - (3) The dimensions of the room(s) concerned.
 - (4) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
 - (5) The make and model of the x-ray equipment and the maximum technique factors.
 - (6) The type of examination(s) or treatment(s) which will be performed with the equipment.
- B. Information on the anticipated workload of the x-ray system(s).
- C. Except as provided for in section F.3.B, a report including all basic assumptions used, shall be submitted with the plans. Any assumptions differing from NCRP 35, Dental X-Ray Protection and/or NCRP 49, Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV, shall be specifically documented and/or explained.

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APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

A. Space Requirements:

- (1) The operator shall be allotted not less than 7.5 square feet (0.697m^2) of unobstructed floor space in the booth.
- (2) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61m).
- (3) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- (4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth.

B. Structural Requirements:

- (1) The booth walls shall be permanently fixed barriers at least 7 feet (2.13m) high.
- (2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- (3) Shielding shall be provided to meet the requirements of Part D of these regulations.

C. X-Ray Control Placement:

- (1) The x-ray control for the system shall be fixed within the booth and:
 - (a) Shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the examining table.
 - (b) Shall allow the operator to use the majority of the available viewing windows.

D. Viewing System Requirements:

- (1) Each booth shall have at least one viewing device which will:
 - (a) be so placed that the operator can view the patient during any exposure, and
 - (b) the device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room can not be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.
- (2) When the viewing system is a window, the following requirements also apply:
 - (a) The viewing area shall be at least 1 square foot (0.0929 m^2).
 - (b) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 m) from the edge of the booth.
 - (c) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.
- (3) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, D.1.
- (4) When the viewing system is by electronic means:
 - (a) the camera shall be so located as to accomplish the general requirements of Appendix B, D.1; and
 - (b) there shall be an alternate viewing system as a back up for the primary system.

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APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.
2. Diseases or conditions for which the x-ray examinations are to be used.
3. Description in detail of the x-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.
6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the x-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the x-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

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APPENDIX D

CHARACTERISTICS FOR QUALIFYING DIAGNOSTIC X-RAY EXPERIENCE FOR RADIOLOGICAL PHYSICISTS

1. Knowledge of physical or natural science, mathematics, or engineering sufficient to understand radiation protection standards, theories, and practices.
2. Knowledge of applicable Maine Regulations for Radiation Protection, Federal Performance Standards and appropriate national guides (e.g. NCRP ,AAPM, etc.) and ability to understand and effectively apply them.
3. Knowledge and ability sufficient to select and operate instrumentation used in diagnostic x-ray radiation protection and to interpret the results.
4. Knowledge and ability sufficient to evaluate the need for shielding and to determine and recommend the types and amounts of shielding required.
5. Knowledge of personnel monitoring devices and the ability to recommend appropriate devices for a specific application.
6. Knowledge and ability sufficient to recognize and anticipate existing and potential radiation safety problems.
7. Knowledge and ability sufficient to evaluate and recommend effective use of protective devices for patients, machine operators and others in the immediate environs of the x-ray source.
8. Knowledge and ability sufficient to calculate external radiation doses, evaluate over-exposures and recommend procedures to reduce any reoccurrence.
9. Knowledge and ability sufficient to evaluate and recommend selection, maintenance and effective use of ancillary equipment (e.g. Q.A. devices).
10. Knowledge and ability sufficient to evaluate and recommend quality assurance procedures to improve diagnostic image quality, reduce unnecessary radiation exposure and reduce facility operating costs.
11. Certification requirements for Radiological Physicists are found in section F.4.A.

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APPENDIX E

CHARACTERISTICS FOR QUALIFYING DIAGNOSTIC X-RAY EXPERIENCE FOR X-RAY TECHNICIANS

1. Knowledge of physical or natural science, mathematics, or engineering sufficient to understand radiation protection standards, theories, and practices.
2. Knowledge of applicable Maine Regulations for Radiation Protection, Federal Performance Standards and appropriate national guides (e.g. NCRP, AAPM, etc.) and ability to understand and effectively apply them.
3. Knowledge and ability sufficient to operate instrumentation used in diagnostic x-ray radiation protection and to interpret the results.
4. Knowledge of personnel monitoring devices and the appropriate devices for specific applications.
5. Knowledge and ability sufficient to recognize and anticipate existing and potential radiation safety problems.
6. Knowledge and ability sufficient to evaluate and recommend effective use of protective devices for patients, machines operators and others in the immediate environs of the x-ray source.
7. Knowledge and ability sufficient to evaluate and recommend selection, maintenance and effective use of ancillary equipment (e.g. Q.A. devices).
8. Certification requirements for X-ray Technicians are found in section F.4.B.

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APPENDIX F

X-RAY REGISTRATION FEES

A. Annual Registration Fee

- (1) Beginning January 1, 2000, all x-ray facilities shall pay a yearly registration fee as specified below.
 - (a) All facilities, except mammographic - \$40.00 per tube; mammographic -\$150.00 for each. See note below. [Note: See definition of mammographic facility, section F.2.A(51)].
 - (b) For new facilities established during any calendar year or existing facilities adding new x-ray machines during any calendar year, the annual fee shall be pro-rated as follows:

| <u>fee:</u> | <u>Percent of annual</u> |
|------------------------------------|--------------------------|
| (i) during January/February..... | 100 |
| (ii) during March/April..... | 80 |
| (iii) during May/June..... | 60 |
| (iv) during July/August..... | 40 |
| (v) during September/December..... | 20 |

The table below shows a pro-rated fee schedule for use in calculating registration fees established after January 1. Mammographic fees are not included in the following table.

- (2) Submit a check payable to the Treasurer of State along with the form indicated if your facility is:

existing: Registration Renewal Form *;

new: "Registration of Radiation Machine Facilities" Form;

additional machines: "Supplemental Sheet" Form.

Note: The registration fee for the mammographic facilities includes the annual registration fee, and the annual inspection of the Quality Assurance Program. The cost of the periodic survey is not included with this fee. The periodic survey (section F.3.C(2)) fee is not governed by these rules.

* **A registration renewal form is not necessary if a device is in storage, thus waiving the applicable fees. To be considered in storage means that the device will not be utilized in any way. The device must be registered with the Agency before being utilized for any reason.**

| NEW FACILITIES | | | | | |
|-----------------|---------------------|----------------|-------------|----------------|-----------------------|
| Number of Tubes | January February | March April | May June | July August | September December |
| | 100% | 80% | 60% | 40% | 20% |
| 1 | \$ 40.00 | \$ 32.00 | \$ 24.00 | \$ 16.00 | \$ 8.00 |
| 2 | \$ 80.00 | \$ 64.00 | \$ 48.00 | \$ 32.00 | \$ 16.00 |
| 3 | \$120.00 | \$ 96.00 | \$ 72.00 | \$ 48.00 | \$ 24.00 |
| 4 | \$160.00 | \$128.00 | \$ 96.00 | \$ 64.00 | \$ 32.00 |
| 5 | \$200.00 | \$160.00 | \$120.00 | \$ 80.00 | \$ 40.00 |
| 6 | \$240.00 | \$192.00 | \$144.00 | \$ 96.00 | \$ 48.00 |
| 7 | \$280.00 | \$224.00 | \$168.00 | \$112.00 | \$ 56.00 |
| 8 | \$320.00 | \$256.00 | \$192.00 | \$128.00 | \$ 64.00 |

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APPENDIX G

QUALITY ASSURANCE FOR FACILITIES PERFORMING DIAGNOSTIC X-RAY

I. INTRODUCTION

A. Purpose

1. This rule describes a basic Radiation Safety/Quality Assurance program and represents only a portion of the Quality Assurance tests your facility may choose to perform as part of an individualized program. The Department of Health and Human Services has implemented this program to reduce radiation exposure and optimize diagnostic x-ray image quality. It is our goal to assist facilities to be more actively involved and responsible for Quality Assurance.
2. All hospitals, outpatient clinics, chiropractic, and private medical facilities, to include State approved screening programs, that are performing diagnostic x-rays on humans, shall establish an active quality assurance program. The QA program will be reviewed throughout the year and inspected by the Department at the same frequency stated in section F.3.C.

B. General Concepts

1. Quality control and quality assurance are not well defined and are often incorrectly used. Quality control is a series of distinct technical procedures, which ensure the production of a satisfactory product. Its aim is to provide quality that is not only satisfactory and diagnostic, but also dependable and economic.
2. Quality assurance is an all-encompassing program, including quality control that extends to administrative, educational and preventive maintenance methods. It includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program, with a view to initiating corrective measures when necessary.

C. ALARA Principle (As Low As Reasonably Achievable)

This QA requirement has been established on the ALARA principle to assure that the benefits of using ionizing radiation exceeds the risks to the individual and the public.

D. Authority.

This program is authorized by 22 MRSA section 674.

II. RADIATION SAFETY/QUALITY ASSURANCE PROGRAMS

A. Radiation Safety/Quality Assurance Committee

1. Each diagnostic facility should establish a committee of individuals to be responsible for Radiation Safety and Quality Assurance. The Committee should be composed of a minimum of one trained licensed professional, the Chief Technologist, and/or the QC technologist. Other individuals, such as hospital administrators and representatives of contracted service companies may also be valuable.
2. This oversight committee shall convene on a frequency adequate to meet their responsibilities, with a minimum of one meeting annually. More frequent meetings will probably be important in the initial stages of this program. The minutes of these meetings shall be kept for a minimum of three years.
3. It is the responsibility of this committee to provide direction to the program, assure that proper documentation and testing is maintained, review the program's effectiveness and determine any changes which should be made.
4. The committee shall establish a Quality Assurance manual with assigned responsibilities recorded in the manual. The responsible individuals must be properly instructed.

F. Appendix G

III. QUALITY ASSURANCE MANUAL

A. Records facilities should include are:

1. List of the individuals or companies responsible for testing, supervising and repairing/or servicing the equipment;
2. List of the tests to be performed and the frequency of performance;
3. Acceptability limits for each test;
4. Description of the procedures to be used for each test;
5. List of the equipment to be tested;
6. Protocol for correction;
7. Reference materials and their location;
8. List of the equipment to be used for testing;
9. Sample forms to be used for each test;
10. Committee organization and duties in writing;
11. Equipment records shall be maintained for each x-ray room and mobile x-ray unit to include exposure ranges;
12. Processor and sensitometer logs to regulate proper processor function to include preventive maintenance;
13. Radiation safety policies and procedures;
14. Repeat/reject analysis yearly;
15. Internal audit to self-assess the quality of mammographic interpretations.

IV. GENERAL MONITORING REQUIREMENTS FOR ALL EQUIPMENT

- #### **A.**
- Each facility shall conduct the following tests, at the frequency specified, and maintain records of the data. The type of tests and the frequency of the tests may be modified if the facility can show that alternate tests or schedules will assure good diagnostic image quality.

Daily

Processor - Speed, contrast, base + fog, solution temperatures

Monthly

Replenishments rates, Phantom image quality check-mammography only

Semi-annually

Safelights
Interlocks
View boxes
Aprons, gloves and drapes

Annually

SID indicators
Film/screen contact
Exposure switches

Fluoroscopic image receptor/x-ray field alignment
Fluoroscopic image resolution
Fluoroscopic timers
Fluoroscopic tabletop rates

Pixel size - CT only
Noise - CT only
Linearity and contrast scale - CT only
Water value - CT only
Spatial uniformity -CT only
Scan width - CT only
Tabletop travel - CT only
Laser alignment - CT only
Dose measurements - CT only

Light field/x-ray field alignment
Positive beam limitation sizing
X-ray field/image receptor alignment
Tomographic equipment
* Radiographic Timers including AEC
* kVp - for all tubes
* mA linearity - for all tubes
* HVL - for all tubes
* Average glandular dose - mammography

* This test is to be conducted yearly for hospital and non-hospital mammographic facilities. For all other radiographic facilities the test frequency shall be the same as the mandatory inspection in accordance with Part F.3.C.3.

V. ADDITIONAL TEST FOR MAMMOGRAPHY EQUIPMENT

A.. Mammographic Equipment. Each mammographic facility shall evaluate the following :

1. Image quality phantom to identify masses and calcifications on a monthly basis. Mobile mammographic units shall perform these tests after each relocation.
2. Average glandular dose calculation yearly.
3. Focal spot size measurement annually.